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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|---|-------------|-----------------------|-------------------------------------|------------------|
| 09/902,287 | 07/10/2001 | Michael Conor Minogue | | 8694 |
| 20999 | 7590 | 10/04/2005 | | |
| FROMMER LAWRENCE & HAUG 745 FIFTH AVENUE- 10TH FL. NEW YORK, NY 10151 | | | EXAMINER MULLEN, KRISTEN DROESCH | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 3762 | |

DATE MAILED: 10/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | | |
|------------------------------|------------------------|--|---------------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 09/902,287 | | MINOGUE ET AL. | |
| | Examiner | | Art Unit | |
| | Kristen Mullen | | 3762 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 9/21/05 (RCE).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-37,39-58 and 60-71 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-11,14-37,39-58 and 60-71 is/are rejected.
- 7) ☒ Claim(s) 12 and 13 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 10 July 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/21/05 has been entered.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1, 3-11, 14-28, 32-39, 44-45, and 48-49 are rejected under 35 U.S.C. 102(b) as being anticipated by Russek (4,381,012).

Regarding claim 1, Russek shows a device including a belt (1); a main locating means (either pair of snaps 51-52, or pair 53, 54) provided on the belt for locating a central electrode (50) substantially about the umbilicus of the subject; and two secondary locating means (55, 56) provided on the belt disposed on opposite sides of and equidistant from the main locating means for locating two corresponding side electrodes of the at least three electrodes, a first of the two side electrodes (placed at 55 or 56) spaced apart from the central electrode (placed at 51-54) in a general direction of towards the left mid-axillary line of the subject and a second of the two side

electrodes (placed at 55 or 56) spaced apart from the central electrode (placed at 51-54) in a general direction of towards the right mid-axillary line or the subject (Fig 7).

Regarding claims 3-5, Russek shows the secondary locating means (55, 56) are disposed on the belt *for* locating the respective side electrodes toward the midpoint of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest, adjacent the corresponding mid-axillary line, and adjacent the midpoint of the corresponding mid-axillary line between the rib cage and the corresponding iliac crest (Fig 7).

With respect to claims 6-7, Russek shows the main locating means (all of the snaps 51-54) is disposed on the belt *for* locating the central electrode on the umbilicus and extending completely around the umbilicus (Fig. 7).

Regarding claims 8-10, Russek shows a reference means (4) *for* locating the belt on the torso relative an anatomic reference, circumferentially around the torso and vertically along the torso (Fig. 7).

With respect to claim 11, Russek shows the main locating means (51-54) act as a reference means *for* locating the belt relative to the umbilicus (Fig. 7). The examiner points out that one can see and feel the locating means on the belt.

The functional language and statements of intended use (such as “for”) have been carefully considered but are not considered to impart any further structural limitations over the prior art.

With respect to claims 14-15, Russek further shows the belt comprises a resilient material being of greater stretchability than that of other materials of the belt (Col. 3, lines 9-50).

Regarding claims 16-17, Russek further shows the main electrically conductive contact means (50) is provided on the belt corresponding to the main locating means and located within and adjacent to the main locating means (54) (Figs. 7-8).

With respect to claims 18- 20, Russek further shows two secondary electrically conductive contact means (50) on the belt, and each secondary contact means (50) is located adjacent the secondary locating means (55, 56) (Col. 5, lines 1-25).

With respect to claims 21-22, Russek further shows each main (either pair of snaps 51-52, or pair 53, 54) and secondary locating means (551-56) is provided as a visually perceptible locating means and formed as a corresponding locating mark on the belt (Fig. 7).

Regarding claim 23, Russek shows each locating means (51-56) is adapted for locating a patch type electrode (50)(Fig. 7).

With respect to claims 24-25, Russek shows at least three patch electrodes (50) are formed as a removable part of the device (Col. 5, lines 1-25; Fig. 7).

Regarding claim 26, Russek shows each side electrode is sized to cover at least a portion of the corresponding lower thoracic nerves and the corresponding second lumbar nerves. The side electrodes of Russek, if applied to the abdomen rather than the back, are of sufficient size to cover at least a portion of the corresponding lower thoracic nerves and the corresponding second lumbar nerves.

With respect to claim 27, Russek shows each central electrode (50 located at 53, 54) is sized to extend substantially across the rectus abdominus muscle (Fig. 9; Col. 10, line 40-Col. 11, line 17). The central electrode of Russek, if applied to the abdomen rather than the back, is of sufficient size to extend *substantially* across the rectus abdominus muscle.

Regarding claim 28, Russek further shows the area of contact of each side electrode (electrodes 50 corresponding to snaps 55, 56) does not exceed the area of contact of the central electrode (electrodes 50, corresponding to snaps 51, 52, 53 and 54) (Figs. 7-8).

With respect to/regarding claims 32 and 37, Russek further shows a receiving means (83) provided in the belt for receiving a signal generating means (82) and the receiving means is a releasable receiving means for releasably receiving the signal generating means (Col. 5, lines 62-68).

Regarding claims 33-36, Russek further shows main and secondary electrical connecting means (8-13) located in the belt and extending between the receiving means and the signal generating means (TENS) and the main contact means and extending between the receiving means and the secondary contact means (Figs. 1, 3, 4-5, 7).

With respect to claim 38-39, Russek further shows the belt comprises a belt (Figs. 1, 3, 7, 9, 12, 13) and a securing means (2, 3).

Regarding claims 40-43, Russek further shows main fastening means comprising stud fasteners (51-54, 61-64) provided corresponding to the main locating means and secondary fastening means comprising stud fasteners (55-56, 65-66) for fastening the respective side electrodes to the belt adjacent the secondary locating means (Figs. 7-11, 18; Col. 5, lines 26-54).

Regarding claim 44, Russek further shows each stud fastener comprises a female (51-56, 61-66) and male part (57, 66') (Figs. 9-10, 18)

With respect to claim 45, Russek further shows each stud fastener is electrically conductive (Col. 5, lines 26-54).

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Regarding claims 48-49, Russek shows each stud fastener comprises a first part (57) for attaching to a corresponding electrode and a second part (51-56, 61-66, 66') for attaching to the belt wherein the first and second parts engage each other with electrically conductive engagement (Figs. 7-11, 18).

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 52-58 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piunti (5,724,996) in view of Russek (4,381,012).

With respect to claim 52, Piunti shows providing at least three electrodes, one electrode being a central electrode and the other two electrodes being side electrodes, providing means (conductor wires 2b) electrically connecting said at least three electrodes and a signal generator, said means enclosed within an belt (insulation of the conductor wires); and passing at least one pulsed signal subcutaneously through the subject between the at least three electrodes (Figs. 2-3, 8; Col. 3, lines 5-25; Col. 4, lines 8-13). Although Piunti fails to show the electrically connecting means are enclosed within a belt, attention is directed to Russek which shows an electrode belt with wires embedded within the belt. Russek implicitly teaches that embedding the wires within the belt eliminates the possibility of tangling of the wires. Therefore it would have been obvious to one with ordinary skill in the art at the time the invention was made to

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modify the method of Piunti to enclose the electrically connecting means (wires) within the belts in order eliminate the possibility of tangling of the wires.

Regarding claim 53-58, the statements of intended use have been carefully considered, but are not deemed to place any further restrictions on the method. The location of the various electrodes on the subject is deemed to be intended use since the steps of placing the various electrodes in the various locations have not been recited.

With respect to claim 60, Piunti further shows the at least one pulsed signal is applied simultaneously to each of the side electrodes (Claims 1, 4).

6. Claim 29 is rejected under 35 U.S.C. 103(a) as being unpatentable over Russek (4,381,012). Russek discloses the claimed invention except for the specific size of the each side electrode. It would have been an obvious matter of design choice to form the side electrode having a width of 50 mm to 150 mm since such a modification would have involved a mere change in the size of a component. A change in size is generally recognized as being within the level of ordinary skill in the art. *In re Rose*, 105 UPSQ 237 (CCPA 1955).

7. Claims 30-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russek (4,381,012) in view of Linder (5,190,036). Russek shows all but the electrodes having a gel type coating provided on a side of each electrode facing away from the belt. Attention is directed to Linder, which shows electrodes with an electrically conductive gel-type coating provided on a side of each electrode facing away from the belt in order for the electrode to make electrical contact with the skin (Col. 3, lines 24-33). Therefore, it would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the device of Russek to

include a conductive gel-type coating provided on a side of each electrode facing away from the belt as Linder teaches in order to make electrical contact with the skin.

8. Claims 46-47, and 50-51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Russek (4,381,012) as applied to claims 44 and 48 above. Russek discloses the claimed invention except for showing the exposed surface of the portions of each stud fastener attached to the belt is of electrically insulating material provided by an electrically insulated coating. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the exposed portions of the stud fasteners as taught by Russek with insulating coatings in order to protect a user who may come into contact with the exposed portions of the stud fasteners from electrical shock.

9. Claims 61-71 are rejected under 35 U.S.C. 103(a) as being unpatentable over Piunti (5,724,996). Piunti discloses the claimed invention except for each pulsed signal comprising a plurality of pulses at intervals in the range of 5 msec to 1000msec, 20 msec to 40 msec, and approximately 30 msec \pm 20%; and adjustable interval; each pulsed signal comprises pulses of duration in the range of 10 μ sec to 200000 μ sec, 50 μ sec to 1000 μ sec, 100 μ sec to 500 μ sec, approximately 300 μ sec \pm 20%; and adjustable duration; and each pulsed signal comprises a plurality of pulses of magnitude in the range of 0 mA to 100 mA and adjustable magnitude. It would have been an obvious design choice to one with ordinary skill in the art at the time of the invention to apply pulses comprising a plurality of pulses at intervals in the range of 5 msec to 1000msec, 20 msec to 40 msec, and approximately 30 msec \pm 20%; and adjustable interval; pulses of duration in the range of 10 μ sec to 200000 μ sec, 50 μ sec to 1000 μ sec, 100 μ sec to 500 μ sec, approximately 300 μ sec \pm 20%; and adjustable duration; and each pulsed signal

comprising a plurality of pulses of magnitude in the range of 0 mA to 100 mA and adjustable magnitude, since applicant has not disclosed that these particular pulse parameters provide any criticality and /or unexpected results and it appears that the invention would perform equally well with any pulses such as the pulses taught by Piunti for improving the muscle tone of the abdomen.

Allowable Subject Matter

10. Claims 12-13 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

11. Applicant's arguments filed 9/21/05 with respect to claims 1, 3-11, 14-39 and 44-51 have been fully considered but they are not persuasive. To further clarify the examiner's position with respect to claim 1, the snaps 53 and 54 together are locating means, or snaps 51 and 52 together are locating means. As such, the snaps 55 and 56 are equidistant from snaps 53 and 54 as a pair, or equidistant from snaps 51 and 52 as a pair.

12. Applicant's arguments with respect to claims 52-58 and 60 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

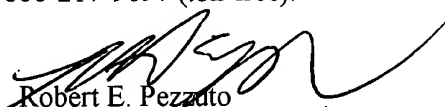
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



kdm



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Art Unit 3762